



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 73, 101, 118, 165, 172, 173, 177, 178, 184, 189, 589, and 700

[Docket No. FDA-2015-N-0011]

Center for Food Safety and Applied Nutrition Library Address; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending certain regulations to update the location of references cited in our food regulations. We are taking this action to reflect the transfer of those references from our facility in College Park, MD, to our library at our main campus in Silver Spring, MD. We also are updating certain regulations to reflect the current names for specific FDA offices.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Center for Food Safety and Applied Nutrition (HFS-024), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-2112.

SUPPLEMENTARY INFORMATION: Various regulations pertaining to human food have incorporated materials by reference. In general, the regulations have identified a library at the Center for Food Safety and Applied Nutrition (CFSAN), which was (at the time the regulations were published) located in Washington, DC, or in College Park, MD. We recently consolidated our library holdings at our main campus in Silver Spring, MD. Consequently, we are making

technical amendments to our regulations at parts 73, 101, 118, 165, 172, 173, 177, 178, 184, 189, 589, and 700 (21 CFR parts 73, 101, 118, 165, 172, 173, 177, 178, 184, 189, 589, and 700) to state that the materials can be found at the FDA Library in Silver Spring, MD. We also are updating certain regulations to reflect the current names for specific FDA offices. The amendments are as follows:

- We are revising §§ 73.165, 73.585, 165.110, and 173.300 to update the library address from "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD" to "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".
- We are revising §§ 101.4, 101.81(c)(2)(ii)(A) introductory text and (B)(1) and (2), 101.83, 165.110, 172.155, 172.785, 172.833, 173.25, 173.45, 173.340, 173.357, 173.370, 177.1350, 177.1360, 177.1390, 177.1520, 177.2600, 178.3297, 184.1063, 184.1148, 184.1150, 184.1250, 184.1387, 184.1420, 184.1444, 184.1866, 189.5, 589.2001, and 700.27 to update the library address from "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740" to "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".
- We are revising §101.80 to update the library address from "Center for Food Safety and Applied Nutrition's Library, Harvey W. Wiley Federal Building, 5100 Paint Branch Pkwy., College Park, MD" to "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".
- We are revising §101.81(c)(2)(ii)(A)(5) to update the library address from "Center for Food Safety and Applied Nutrition Library, 5100 Paint Branch Pkwy., College Park, MD

20740" to "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

- We are revising §§ 118.8 and 165.110 to update the library address from "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD, 301-436-2163" to "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".
- We are revising § 165.110 to update the library address from "Center for Food Safety and Applied Nutrition's Library, 200 C St. NW., Washington DC" to "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".
- We are revising §§ 165.110, 172.723, 172.736, 172.804, 172.809, 172.864, 172.886, 173.375, 177.1345, 177.1585, 177.1637, 178.1010, 184.1007, 184.1257, 184.1259, 184.1282, 184.1293, 184.1472, 184.1530, 184.1699, 184.1979, 184.1979a, 184.1979b, and 184.1979c to update the library address from "Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740" to "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".
- We are revising §§ 172.167 and 173.356 to update the library address from "Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2163" to "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

- We are revising § 172.736 to update the library address from "in the library at the Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740" to "at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".
- We are revising § 172.829 to update the library address from "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., rm. 1C-100, College Park, MD 20740" to "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".
- We are revising § 173.325 to update the library address from "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740 20204-0001" to "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".
- We are revising § 184.1311 to update the library address from "Center for Food Safety and Applied Nutrition's library, 5100 Paint Branch Pkwy., College Park, MD 20740" to "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".
- We are revising § 101.83(c)(2)(ii)(A)(2) and (c)(2)(ii)(B)(2), to remove the words "Office of Nutritional Products, Labeling, and Dietary Supplements, Division of Nutrition Science and Policy," and in their place add "Office of Nutrition, Labeling and Dietary Supplements, Nutrition Programs Staff".
- We are revising § 118.8 to replace "The FDA" with "FDA" .
- We are revising § 173.300 to add the words "Office of Food Additive Safety".

- We are revising § 173.340 to remove the words "Division of Petition Control" and "(HFS-215)" and in their place adding "Office of Food Additive Safety (HFS-200)".
- We are revising § 173.357 to remove the words "Division of Petition Control" and "(HFS-215)" and in their place adding "Office of Food Additive Safety (HFS-200)".
- We are updating §§ 177.1520 and 177.1585 to remove the words "Office of Premarket Approval" and in their place adding the "Office of Food Additive Safety".

Publication of this document constitutes final action of these changes under the Administrative Procedure Act (5 U.S.C. 553). These amendments are merely updating the address of CFSAN references and the names of CFSAN offices. FDA, therefore, for good cause, finds under 5 U.S.C. 553(b)(3)(B) and (d)(3) that notice and public comment are unnecessary.

List of Subjects

21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

21 CFR Part 118

Egg and egg products, Incorporation by reference, Recordkeeping requirements, Safety.

21 CFR Part 165

Beverages, Bottled water, Food grades and standards, Incorporation by reference.

21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

21 CFR Part 173

Food additives.

21 CFR Part 177

Food additives, Food packaging.

21 CFR Part 178

Food additives, Food packaging.

21 CFR Part 184

Food additives.

21 CFR Part 189

Food additives, Food packaging.

21 CFR Part 589

Animal feeds, Animal foods, Food additives.

21 CFR Part 700

Cosmetics, Packaging and containers.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR parts 73, 101, 118, 165, 172, 173, 177, 178, 184, 189, 589, and 700 are amended as follows:

PART 73--LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

1. The authority citation for 21 CFR part 73 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

§ 73.165 [Amended]

2. Amend § 73.165 in paragraph (b) by removing "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD" and adding in its place "Food

and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 73.585 [Amended]

3. Amend § 73.585 in paragraph (b) by removing "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

PART 101--FOOD LABELING

4. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

§ 101.4 [Amended]

5. Amend § 101.4 in paragraphs (h) introductory text and (h)(2) by removing "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740" wherever it appears and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 101.80 [Amended]

6. Amend § 101.80 in paragraph (c)(2)(iii)(C) by removing "Center for Food Safety and Applied Nutrition's Library, Harvey W. Wiley Federal Building, 5100 Paint Branch Pkwy., College Park, MD" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 101.81 [Amended]

7. Amend § 101.81 as follows:

a. In paragraphs (c)(2)(ii)(A) introductory text and (c)(2)(ii)(B)(1) and (2) remove "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740" wherever it appears and add in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

b. In paragraph (c)(2)(ii)(A)(5) remove "Center for Food Safety and Applied Nutrition Library, 5100 Paint Branch Pkwy., College Park, MD 20740" and add in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 101.83 [Amended]

8. Amend § 101.83 in paragraphs (c)(2)(ii)(A)(2) and (c)(2)(ii)(B)(2) as follows:

a. Remove "Office of Nutritional Products, Labeling, and Dietary Supplements, Division of Nutrition Science and Policy" and add in its place "Office of Nutrition, Labeling and Dietary Supplements, Nutrition Programs Staff".

b. Remove "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740" wherever it appears and add in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

PART 118--PRODUCTION, STORAGE, AND TRANSPORTATION OF SHELL EGGS

9. The authority citation for 21 CFR part 118 continues to read as follows:

Authority: 21 U.S.C. 321, 331-334, 342, 371, 381, 393; 42 U.S.C. 243, 264, 271.

§ 118.8 [Amended]

10. Amend § 118.8 in paragraphs (a) and (b) as follows:

a. Remove "The FDA" wherever it appears and add in its place "FDA".

b. Remove "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD, 301-436-2163" wherever it appears and add in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

PART 165--BEVERAGES

11. The authority citation for 21 CFR part 165 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 343, 343-1, 348, 349, 371, 379e.

§ 165.110 [Amended]

12. Amend § 165.110 as follows:

a. In paragraphs (a)(2)(iv) and (vii), (b)(4)(iii)(E)(7)(iv), and (b)(4)(iii)(I), remove "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740" wherever it appears and add in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

b. In paragraphs (b)(2)(ii) and (b)(3) introductory text, remove "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2163" wherever it appears and add in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

c. In paragraph (b)(4)(i)(C) introductory text, remove "Center for Food Safety and Applied Nutrition's Library, 200 C St. NW., Washington DC" and add in its place "Food and

Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039."

d. In paragraphs (b)(4)(iii)(E) introductory text, (b)(4)(iii)(E)(1)(ii) and (iv), (b)(4)(iii)(E)(11)(i), (b)(4)(iii)(E)(14)(i), and (b)(4)(iii)(F)(20), remove "Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740" wherever it appears and add in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

e. In paragraph (b)(5)(ii) introductory text, remove "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD" and add in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

PART 172--FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

13. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

§ 172.155 [Amended]

14. Amend § 172.155 in paragraph (c) by removing "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 172.167 [Amended]

15. Amend § 172.167 in paragraph (d)(2) by removing "Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2163" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 172.723 [Amended]

16. Amend § 172.723 in paragraph (b)(3) by removing "Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 172.736 [Amended]

17. Amend § 172.736 as follows:

a. In paragraph (b)(1), remove "Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740" and add in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

b. In paragraph (b)(3), remove "in the library at the Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740" and add in its place "at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 172.785 [Amended]

18. Amend § 172.785 in paragraph (b)(1) by removing "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 172.804 [Amended]

19. Amend § 172.804 in paragraph (c)(2) by removing "Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 172.809 [Amended]

20. Amend § 172.809 in paragraph (b) introductory text by removing "Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 172.829 [Amended]

21. Amend § 172.829 in paragraph (b) introductory text by removing "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., rm. 1C-100, College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 172.833 [Amended]

22. Amend § 172.833 in paragraphs (b)(2) and (4) by removing "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740" wherever it appears and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 172.864 [Amended]

23. Amend § 172.864 in paragraph (a)(3) by removing "Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 172.886 [Amended]

24. Amend § 172.886 in paragraph (c)(2)(iii) by removing "Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

PART 173--SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR
HUMAN CONSUMPTION

25. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

§ 173.25 [Amended]

26. Amend § 173.25 in paragraph (b)(2)(ii)(B) by removing "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 173.45 [Amended]

27. Amend § 173.45 in paragraph (a) by removing "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 173.300 [Amended]

28. Amend § 173.300 in paragraph (a)(2) as follows:

a. Remove "Center for Food Safety and Applied Nutrition (HFS-200)" and add in its place "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition".

b. Remove "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD" and add in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 173.325 [Amended]

29. Amend § 173.325 in paragraph (h) by removing "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740 20204-0001" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

30. Amend § 173.340 in the table in paragraph (a)(4) by revising the entry “n-Butoxypoly(oxyethylene)-poly(oxypropylene)glycol” to read as follows:

§173.340 Defoaming agents.

* * * * *

(a) * * *

(4) * * *

Substances	Limitations
<p><u>n</u>-Butoxypoly(oxyethylene)-poly(oxypropylene)glycol</p>	<p>Viscosity range, 4,850-5,350 Saybolt Universal Seconds (SUS) at 37.8 °C (100 °F). The viscosity range is determined by the method “Viscosity Determination of <u>n</u>-butoxypoly(oxyethylene)-poly(oxypropylene) glycol” dated April 26, 1995, developed by Union Carbide Corp., P.O. Box 670, Bound Brook, NJ 08805, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the material incorporated by reference are available from the Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, and may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of</p>

	<p>this material at NARA, call 202-741-6030, or go to:</p> <p>http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.</p>
* * *	* * * *

* * * * *

§ 173.356 [Amended]

31. Amend § 173.356 in paragraph (a) by removing "Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2163" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

32. Amend § 173.357 in the table in paragraph (a)(2) by revising the entry "Polyethylenimine reaction product with 1,2-dichloroethane (CAS Reg. No. 68130-97-2)" to read as follows:

§173.357 Materials used as fixing agents in the immobilization of enzyme preparations.

* * * * *

(a) * * *

(2) * * *

Substances	Limitations
* * *	* * * *
Polyethylenimine reaction product with 1,2-	May be used as a fixing material in the

<p>dichloroethane (CAS Reg. No. 68130-97-2) is the reaction product of homopolymerization of ethylenimine in aqueous hydrochloric acid at 100 °C and of cross-linking with 1,2-dichloroethane. The finished polymer has an average molecular weight of 50,000 to 70,000 as determined by gel permeation chromatography. The analytical method is entitled "Methodology for Molecular Weight Detection of Polyethylenimine," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740, and may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or</p>	<p>immobilization of glucoamylase enzyme preparations from <u>Aspergillus niger</u> for use in the manufacture of beer.</p> <p>May be used as a fixing material in the immobilization of:</p> <ol style="list-style-type: none"> 1. Glucose isomerase enzyme preparations for use in the manufacture of high fructose corn syrup, in accordance with §184.1372 of this chapter. 2. Glucoamylase enzyme preparations from <u>Aspergillus niger</u> for use in the manufacture of beer. Residual ethylenimine in the finished polyethylenimine polymer will be less than 1 part per million as determined by gas chromatography-mass spectrometry. The residual ethylenimine is determined by an analytical method entitled "Methodology for Ethylenimine Detection in Polyethylenimine," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Residual 1,2-dichloroethane in the finished polyethylenimine polymer will be less than 1 part per million as determined by gas
---	---

<p>go to:</p> <p><u>http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html</u>.</p>	<p>chromatography. The residual 1,2-dichloroethane is determined by an analytical method entitled, "Methodology for Ethylenedichloride Detection in Polyethylenimine," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:</p> <p><u>http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html</u>.</p>
--	---

* * * * *

33. Amend § 173.370 in paragraph (c) by removing "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 173.375 [Amended]

34. Amend § 173.375 in paragraph (a) by removing "Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

PART 177--INDIRECT FOOD ADDITIVES: POLYMERS

35. The authority citation for 21 CFR part 177 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

§ 177.1345 [Amended]

36. Amend § 177.1345 in paragraph (b)(1) by removing "Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 177.1350 [Amended]

37. Amend § 177.1350 in paragraph (b)(2) by removing "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 177.1360 [Amended]

38. Amend § 177.1360 in paragraph (d) by removing "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 177.1390 [Amended]

39. Amend § 177.1390 in paragraph (c)(3)(i)(a)(1) by removing "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

40. Amend § 177.1520 in the table in paragraph (b) by revising the entry “Methyl methacrylate/butyl acrylate-grafted polypropylene copolymer containing methyl methacrylate/butyl acrylate-grafted polypropylene (CAS Reg. No. 121510-09-6)” to read as follows:

§177.1520 Olefin polymers.

* * * * *

(b) * * *

Substance	Limitations
* * *	* * * *
Methyl methacrylate/butyl acrylate-grafted polypropylene copolymer containing methyl methacrylate/butyl acrylate-grafted polypropylene (CAS Reg. No. 121510-09-6), methyl methacrylate/butyl acrylate copolymer	For use only at levels not to exceed 6 percent by weight of olefin polymers complying with paragraph (c) of this section, items 1.1, 3.1a, 3.2a, and 3.2b, where the copolymers complying with items 3.1a, 3.2a, and 3.2b

<p>(CAS Reg. No. 25852-37-3), methyl methacrylate homopolymer (CAS Reg. No. 9011-14-7), and polypropylene (CAS Reg. No. 9003-07-0), resulting from the reaction of a mixture of methyl methacrylate and butyl acrylate with polypropylene. The finished product contains no more than 55 percent by weight of polymer units derived from methyl methacrylate and butyl acrylate as determined by a method entitled, "Determination of the Total Acrylic in PP-MMA/BA Polymers," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Food Additive Safety, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration</p>	<p>contain not less than 85 weight-percent of polymer units derived from propylene.</p>
--	---

(NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html .	
* * *	* * * *

* * * * *

§ 177.1585 [Amended]

41. Amend § 177.1585 in paragraph (c)(1)(i) as follows:

a. Remove "Office of Premarket Approval" and add in its place "Office of Food Additive Safety".

b. Remove "Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740" and add in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 177.1637 [Amended]

42. Amend § 177.1637 in paragraph (b)(2) by removing "Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 177.2600 [Amended]

43. Amend § 177.2600 in paragraph (c)(4)(i) by removing "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

PART 178--INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND
SANITIZERS

44. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

§ 178.1010 [Amended]

45. Amend § 178.1010 in paragraph (c)(40) by removing "Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 178.3297 [Amended]

46. Amend § 178.3297 in the table in paragraph (e) by revising the entry "High-purity furnace black (CAS Reg. No. 1333-86-4)" to read as follows:

§178.3297 Colorants for polymers.

* * * * *

(e) * * *

Substances	Limitations
* * *	* * * *
High-purity furnace black (CAS Reg. No. 1333-86-4) containing total polynuclear	For use at levels not to exceed 2.5 percent by weight of the polymer.

aromatic hydrocarbons not to exceed 0.5 parts per million, and benzo[a]pyrene not to exceed 5.0 parts per billion, as determined by a method entitled "Determination of PAH Content of Carbon Black," dated July 8, 1994, as developed by the Cabot Corp., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

* * *

* * * *

PART 184--DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED
AS SAFE

47. The authority citation for 21 CFR part 184 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371.

§ 184.1007 [Amended]

48. Amend § 184.1007 in paragraph (b)(1) by removing "Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 184.1063 [Amended]

49. Amend § 184.1063 in paragraphs (b) introductory text and (b)(8) by removing "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740" wherever it appears and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 184.1148 [Amended]

50. Amend § 184.1148 in paragraph (b) by removing "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 184.1150 [Amended]

51. Amend § 184.1150 in paragraph (b) by removing "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 184.1250 [Amended]

52. Amend § 184.1250 in paragraph (b) by removing "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 184.1257 [Amended]

53. Amend § 184.1257 in paragraph (b) by removing "Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 184.1259 [Amended]

54. Amend § 184.1259 in paragraph (b)(3) by removing "Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 184.1282 [Amended]

55. Amend § 184.1282 in paragraph (b) by removing "Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College

Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 184.1293 [Amended]

56. Amend § 184.1293 in paragraph (b) by removing "Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039."

§ 184.1311 [Amended]

57. Amend § 184.1311 in paragraph (b) by removing "Center for Food Safety and Applied Nutrition's library, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039."

§ 184.1387 [Amended]

58. Amend § 184.1387 in paragraph (b) by removing "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 184.1420 [Amended]

59. Amend § 184.1420 in paragraph (b) by removing "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 184.1444 [Amended]

60. Amend § 184.1444 in paragraph (b)(3) by removing "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 184.1472 [Amended]

61. Amend § 184.1472 in paragraph (a)(2)(iii) by removing "Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 184.1530 [Amended]

62. Amend § 184.1530 in paragraph (b) by removing "Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 184.1699 [Amended]

63. Amend § 184.1699 in paragraph (b) by removing "Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 184.1866 [Amended]

64. Amend § 184.1866 in paragraph (b) by removing "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in

its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 184.1979 [Amended]

65. Amend § 184.1979 in paragraphs (b)(1) and (2) by removing "Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740" wherever it appears and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 184.1979a [Amended]

66. Amend § 184.1979a in paragraphs (b)(1) introductory text and (b)(2) by removing "Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740" wherever it appears and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 184.1979b [Amended]

67. Amend § 184.1979b in paragraphs (b)(1) introductory text and (b)(2) by removing "Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740" wherever it appears and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

§ 184.1979c [Amended]

68. Amend § 184.1979c in paragraphs (b)(1) introductory text and (b)(2) by removing "Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100

Paint Branch Pkwy., College Park, MD 20740" wherever it appears and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

PART 189--SUBSTANCES PROHIBITED FROM USE IN HUMAN FOOD

69. The authority citation for 21 CFR part 189 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371, 381.

§ 189.5 [Amended]

70. Amend § 189.5 in paragraph (a)(6) by removing "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

PART 589--SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED

71. The authority citation for 21 CFR part 589 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 371.

§ 589.2001 [Amended]

72. Amend § 589.2001 in paragraph (b)(1)(vi)(B) by removing "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

PART 700--GENERAL

73. The authority citation for 21 CFR part 700 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 352, 355, 361, 362, 371, 374.

§ 700.27 [Amended]

74. Amend § 700.27 in paragraph (a)(6) by removing "Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740" and adding in its place "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039".

Dated: January 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-01787 Filed: 2/2/2016 8:45 am; Publication Date: 2/3/2016]